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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/081,393 | 02/20/2002 | Larry E. Morrison | 01886-071001/ V0079 | 1580 |
| 26161 | 7590 | 11/07/2003 | EXAMINER | |
| FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110 | | | CHAKRABARTI, ARUN K | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1634 | |

DATE MAILED: 11/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | |
|--------------------------------------|---------------------------------|---|
| Application No. 10/081,393 | Applicant(s) Morrison | Examiner Arun Chakrabarti |
| | |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Oct 8, 2003
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) 8-20 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) Interview Summary (PTO-413) Paper No(s). _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: *Detailed Action*

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DETAILED ACTION

Current status of the Application

1. Claim 1 has been amended. Currently claims 1-20 are pending in this application. Claims 8-20 are withdrawn from further consideration. Therefore, claims 1-7 are under consideration.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7 are rejected under 35 U.S.C. 102 (b) as being anticipated by Pinkel et al. (U.S. Patent 5,856,097) (January 5, 1999).

This rejection is based on the fact that “comprising” language of the claims allows any other step(s) or material(s) to be added in the claimed invention.

Pinkel et al. teaches a set of chromosomal probes comprising a 5p chromosomal probe and a probe selected from 17q21 locus specific probe as well as 8q24 locus specific probe and chromosome 17 enumeration probe (Column 48, Table 4).

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Pinkel et al. teaches the set of chromosomal probes, wherein different detection moieties are coupled to the two probes comprising fluorescent labels (Column 51, line 8 to column 52, line 42 and Figures 2, 5, and 6).

Pinkel et al inherently teaches the set of chromosomal probes comprising a 5p probe, a 8q24 locus specific probe and 7p probe and 17q21 locus specific probe (Column 48, Table 4 and Figure 17).

Pinkel et al inherently teaches the set of chromosomal probes comprising a 5p probe, a 8q24 locus specific probe and 20q chromosome arm probe and 7p locus specific probe (Column 48, Table 4 and Figure 17).

This inherency is based on the fact that Pinkel et al teaches broadly all chromosomal probes (Figure 17) as Pinkel states, "When CGH is applied, for example, in the fields of tumor cytogenetics and prenatal diagnosis, it provides methods to determine whether there are abnormal copy numbers of nucleic acid sequences *anywhere* in the genome of a subject tumor cell or fetal cell or the genomes from representative cells from a tumor cell population or from a number of fetal cells, without having to prepare condensed chromosome spreads from those cells (Column 3, lines 32-39)". Although the specific numbers such as 5p15 and 7p12 are not mentioned by Pinkel et al., these probes are inherently present in the combination of probes of Pinkel et al because "it provides methods to determine whether there are abnormal copy numbers of nucleic acid sequences *anywhere* in the genome of a subject tumor cell".

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Moreover, MPEP 2123 also states “A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 10 USPQ2d 1843 (Fed. Cir. 1989).” Although Pinkel et al. reference uses certain combination of probes to detect certain loci on the chromosome, Pinkel et al teaches that such probes can detect abnormal copy numbers of nucleic acid sequences *anywhere* in the genome of a subject tumor cell. Moreover, MPEP 2111 states, “Claims must be given their broadest reasonable interpretation. During patent examination, the pending claims must be “given the broadest reasonable interpretation consistent with the specification”. Applicant always has the opportunity to amend the claims during prosecution and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than it is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969)”. In this case, in presence of “comprising” language of the claims, any combination of probes as taught by Pinkel et al., can be used for detecting abnormal copy numbers of nucleic acid sequences *anywhere* in the genome of a subject tumor cell.

Response to Amendment

4. In response to amendment, previous 102(b) and 103(a) rejections are hereby withdrawn.

Response to Arguments

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.5. Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group LIE Chantae Dessau whose telephone number is (703) 605-1237.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 is (703) 872-9306. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

ARUN K. CHAKRABARTI
Arun Chakrabarti **PATENT EXAMINER**
Patent Examiner
Art Unit 1634

November 4, 2003

Gary Benzion
GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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| Notice of References Cited | | Application/Control No. 10/081,393 | Applicant(s)/Patent Under Reexam Morrison | |
| Examiner Arun Chakrabarti | | Art Unit 1634 | Page 1 of 1 | |

U.S. PATENT DOCUMENTS

| | Document Number Country Code-Number-Kind Code | Date MM-YYYY ¹ | Name | Classification ² | |
|---|--|------------------------------|--------|-----------------------------|---|
| * | A 5,856,097 | 1/1999 | Pinkel | 435 | 6 |
| B | | | | | |
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| E | | | | | |
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FOREIGN PATENT DOCUMENTS

| | Document Number Country Code-Number-Kind Code | Date MM-YYYY ¹ | Country | Name | Classification ² | |
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NON-PATENT DOCUMENTS

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|---|--|
| | Include, as applicable: Author, Title, Date, Publisher, Edition or Volume, Pertinent Pages |
| U | |
| V | |
| W | |
| X | |

* A copy of this reference is not being furnished with this Office action. See MPEP § 707.05(a).

¹ Dates in MM-YYYY format are publication dates.

² Classifications may be U.S. or foreign.

